DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

December 20, 2004

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 05-09

Albert Pierre Marchand, Jr., President
Jessie's Ilwaco Fish Company, Inc.
117 Howerton Way
Ilwaco, Washington 98624

WARNING LETTER

Dear Mr. Marchand:

On July 29, 2004, we inspected your seafood processing facility located at 117 Howerton Way, Ilwaco, Washington. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123).

In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with 21 CFR 123.6 or to otherwise operate in accordance with the requirements of 21 CFR Part 123, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your fresh/frozen tuna, sardines, and shrimp are adulterated in that these products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act, the Seafood HACCP regulations, and the Fish and Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001 (the Hazard Guide) through links in FDA's homepage at www.fda.gov.

The deviations observed are as follows:

- You must have a HACCP plan that, at a minimum, lists the critical limits that must be met at each of the critical control points, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety

hazard." However, your firm's HACCP plans for albacore tuna and sardines list critical limits that are inadequate to control for the food safety hazard of scrombrotoxin formation.

Specifically, the critical limit at the receiving control point listed in your firm's albacore tuna HACCP plan states: "At receiving look at fish and check odor, looking for signs of decomposition." Your firm's HACCP plan for sardines states the critical limit at the receiving control point as: "Product Received at <[redacted]F." Please refer to the Hazard Guide, Chapter 7, Histamines for recommendations regarding harvest vessel records, histamine testing, and criteria for testing for decomposition of lots.

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points for each of the identified food safety hazards, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as "a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for sardines does not list a critical control point for cold storage after receipt for the control of histamine.

- Because you chose to include corrective actions in your HACCP plan, your corrective action plans must be appropriate for a deviation from a critical limit, to comply with 21 CFR 123.7(b). However, your corrective action plans for albacore and shrimp at the "Chilled Storage" critical control point are not appropriate because they do not indicate how you will prevent the distribution of adulterated product in interstate commerce.

We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your product(s) or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plans or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for assuring that your processing plant operates in compliance with the Act and the Seafood HACCP regulation. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Elrand at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

cc: WSDA with disclosure statement